

Appl. No. 10/652,498
Amendment dated January 13, 2006
Amendment

AMENDMENTS TO THE DRAWINGS:

In accompanying sheet of drawings includes a change to Figure 2. This sheet, which includes Figures 1-3, replaces the original sheet including Figures 1-3.

Attachment: one (1) replacement sheet and one annotated sheet showing corrections in red

REMARKS

In the November 3, 2005 Office Action, objections were raised with respect to amendments filed on September 3, 2003 (and in the parent case on October 16, 2001)¹. The drawings were objected to and claims 1-3 and 8-20 stand rejected in view of prior art. Finally, claims 8, 9, 19 and 20 were rejected, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. No other objections or rejections were made in the Office Action.

The Office Action is silent with respect to the claim amendments filed on January 23, 2004. Since the claim amendments filed on January 23, 2004 are available for downloading in the P.A.I.R. system, Applicant assumes the Examiner has considered them in the Office Action. However, Applicant respectfully requests confirmation of consideration of the January 23, 2004 claim amendments.

Status of Claims and Amendments

In response to the November 3, 2005 Office Action, Applicant has submitted one replacement sheet of drawings, including Figures 1-3. None of the claims are being amended by the current Response. Thus, claims 1-3 and 8-20 are pending, with claim 1 being the only independent claim. Reexamination and reconsideration of the pending claims are respectfully requested, particularly in view of the following comments. As mentioned above, the claims amended in the paper filed on January 23, 2004.

¹ Preliminary Amendment was also filed on January 23, 2004

Drawings

On page 2 of the Office Action, the drawings were objected to as failing to comply with 37 CFR §1.83(a). In response, Applicant has filed herewith a Request for Approval of Proposed Drawing Corrections and one (1) sheet of corrected drawings including Figures 1-3 and one (1) marked-up sheet of drawings indicating in red ink the corrections made. Specifically, Figure 2 has been modified to show the stiffening element applied to the balloon, as set forth in the claims. The stiffening element is shown in dotted lines and labeled with numeral 16. Applicant believes that the drawings now comply with 37 CFR §1.83(a) and 37 C.F.R. §1.121(f). Applicant respectfully requests withdrawal of the objections. Applicant also respectfully requests approval and entrance of the one (1) replacement sheet of drawings, including Figures 1-3.

Previously Filed Amendment

On page 3 of the Office Action, the amendments filed on September 2, 2003 and October 16, 2001 were objected to as allegedly introducing new matter into the disclosure. Specifically, the Office Action alleges that the claimed (foil or) coating materials consisting of a biological material, a ceramic, a metallic, or elastomer, constitute new matter. For the reasons set forth below, Applicant respectfully traverses the objections.

The MPEP §608.01(l) states that:

In establishing a disclosure, Applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it. (emphasis added).

The subject matter of the amendments to the specification filed on September 2, 2003 and October 16, 2001 relating to the objected to foil or coating materials are taken directly from originally filed claims 4-7 (now canceled). It should be noted that originally filed

claims 4-7 are multiple dependent claims providing support for various combinations of the recited features. The original claim language copied to the amended specification has not been reworded or paraphrased. The amendments to the specification do not deviate from the originally filed claims nor do they go beyond the scope of the originally filed claims. Since the claims are part of the originally filed specification, no new subject matter has been introduced into the specification by the previous amendments. Therefore, Applicant respectfully asserts that the objection is in error and should be withdrawn.

Claim Rejections - 35 U.S.C. §112

On pages 2-3 of the Office Action, claims 8, 9, 19 and 20 were rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully traverses this rejection, particularly in view of the following comments.

Specifically, MPEP §608.01(l) states that:

In establishing a disclosure, Applicant may rely not only on the description and drawing as filed but also on the original claims if their content justifies it.

Where subject matter not shown in the drawing or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and requirement made to amend the drawing and description to show this subject matter. The claim should not be attacked either by objection or rejection because this subject matter is lacking in the drawing and description. It is the drawing and description that are defective, not the claim.

It is, of course, to be understood that this disclosure in the claim must be sufficiently specific and detailed to support the necessary amendment of the drawing and description. (emphasis added).

Applicant respectfully submits that the claims 8, 9, 19 and 20 that were added in the Preliminary Amendment of September 2, 2003 are fully supported in the originally filed patent application, e.g., in claims 4-7 of the originally filed patent application. It should be

noted that cancelled claims 4-7 as originally filed included multiple dependencies providing full support for the various combination of features, including those recited in claims 8, 9, 19 and 20. Thus, these claim limitations were in Applicant's possession at the time the application was filed. Moreover, Applicant has added the subject matter of original claims 4-7 to the specification by the September 2, 2003 Amendment to provide clear antecedent basis for these claims. To the extent that this rejection asserts non-enablement, Applicant respectfully submits that the level of skill is quite high in the stent art such that specific examples are not necessary. Thus, according to MPEP §608.01(l), since Applicant may rely on claims 1-7 of the originally filed application and Applicant has added the subject matter from these claims to the specification, Applicant respectfully submits that the 35 U.S.C. §112, first paragraph, rejection is *improper*. Accordingly, Applicant believes that the claims comply with 35 U.S.C. §112, first paragraph. Withdrawal of the rejections is respectfully requested.

Rejections - 35 U.S.C. § 103

On pages 4-5 of the Office Action, claims 1-3 and 8-20 stand rejected under 35 U.S.C. §103(a). More specifically, claims 1-3, 8 and 9 stand rejected as being unpatentable over U.S. Patent No. 6,120,534 (Ruiz) in view of European Patent Publication No. 779,062 (Glastra et al.), claims 1-3, 8, 9 and 13-15 stand rejected as being unpatentable over the Glastra patent in view of DE Patent Document 195 09 464 (Jaeger et al.) and claims 10-12, and 16-20 stand rejected as being unpatentable over the Glastra et al. document in view of Jaeger et al. and U.S. Patent No. 5,695,498 (Tower). In response, Applicant respectfully traverses the rejection for the reasons set forth below.

More specifically, independent claim 1, requires a stent-catheter arrangement that has a catheter including (1) *an expandable balloon having fully expandable first and second ends and a section of reduced expandability* between the first and second ends; and a stent disposed on the expandable balloon. The stent recited in claim 1 includes a liquid impermeable cover dimensioned and configured to extend over the section of reduced expandability and portions of the first and second fully expandable sections of the balloon. The balloon and the stent of claim 1 are further configured and arranged to (3) expand the stent to form *first and second expanded fixing portions and a smaller radial width throttle portion* between the first and second expanded fixing portions.

Contrary to the conclusions in the Office Action, Applicant asserts that the specific claimed arrangement is *not* disclosed or suggested by the Ruiz patent, the Glastra et al publication or the Jaeger publication whether taken singularly or in combination. The expanded stent as shown in Figure 3 of the present application can not be formed by the combination of references as set forth in the Office Action.

First, as acknowledged in the Office Action, the Ruiz patent *does not* disclose a stent-catheter having a single balloon with fully expandable first and second ends. Rather, the Ruiz patent *requires* the use of a catheter having two separate balloons 25 and 26 that are inflated via two independent inflation lumens 23 and 24 (see Figure 3 and column 4 lines 33-43). Further, the Ruiz patent *requires* the use of a stent pre-formed with a constricted region 13 such that upon inflation, one or more of the end lobes 11 and 12 of the stent have a greater diameter than the constricted region 13. Clearly, the Ruiz patent teaches away from the present invention by requiring a complex balloon inflation structure on the catheter and a complex stent structure.

Second, the Glastra et al. publication *fails* to provide for the deficiencies of the Ruiz patent. While the Ruiz patent discloses a complex stent and a complex balloon structure, the Glastra et al. reference teaches a single balloon 6 and a generally uniform diameter tubular element 4 that are inserted into a patient. Further, the stent-catheter structure disclosed in the Glastra et al. reference relies solely on the conditions within a patient to achieve a reduced diameter portion of a subsequently formed stent. The tubular element 4 of Glastra et al. requires the presence of anomalies such as a tumor 2 within the patient in order to achieve a stent having end portions with a large diameter and a reduced diameter portion therebetween. In the absence of such an anomaly, the formed stent could have a uniform diameter throughout its length. There is nothing in the disclosed catheter-stent structure of Glastra et al. that teaches or suggests the catheter-stent structure of the claimed invention. Clearly, there is no motivation to combine simple catheter-stent structure taught by Glastra et al. with the complex structure of the stent and catheter of Ruiz to achieve the claimed invention.

The present invention does not require the presence of a tumor or other anomaly within a patient to achieve the recited shape of the subsequently formed stent. The present invention relies on a catheter having an *expandable balloon* having *fully expandable first and second ends* and a *section of reduced expandability* between the first and second ends in order to form the stent. Further, the present invention does not require the multiple balloons of Ruiz to achieve the claimed invention. For this reason and others, Applicant respectfully traverses the rejection and asserts that claim 1 is allowable over the cited prior art.

Third, the Jaeger et al. reference *fails* to disclose or suggest a catheter having an *expandable balloon* having *fully expandable first and second ends* and a *section of reduced expandability* between the first and second ends as claimed. Indeed, the Jaeger et al. reference is silent with respect to a catheter structure. Accordingly, if the teachings of the

Jaeger et al. reference were applied to the teachings of the Glastra et al. reference, the resulting hypothetical device would not have an *expandable balloon* having *fully expandable first and second ends* and a *section of reduced expandability* between the first and second ends as claimed in the instant application.

Therefore, Applicant respectfully asserts that the cited combinations of these three references would *not* produce a hypothetical device that would meet the claimed invention as set forth in independent claim 1.

It is well settled in U.S. patent law that the mere fact that the prior art can be modified *does not* make the modification obvious, unless the prior art suggests the desirability of the modification. Accordingly, the prior art of record lacks any suggestion or expectation of success for combining the patents to create the Applicant's unique arrangement of the stent and balloon as set forth in independent claim 1.

Moreover, Applicant believes that the dependent 2-3 and 8-20 are also allowable over the prior art of record in that they depend from independent claim 1, and therefore are allowable for the reasons stated above. Also, the dependent claims 2-3 and 8-20 are further allowable because they include additional limitations. Thus, Applicant believes that since the prior art of record does not disclose or suggest the invention as set forth in independent claim 1, the prior art of record also fails to disclose or suggest the inventions as set forth in the dependent claims.

For these reasons and others, Applicant respectfully asserts that claims 1-3 and 8-20 clearly distinguish the present invention over the Ruiz, Glastra et al. and Jaeger et al. reference. Therefore, Applicant respectfully requests that this rejection be withdrawn in view of the above comments and amendments.

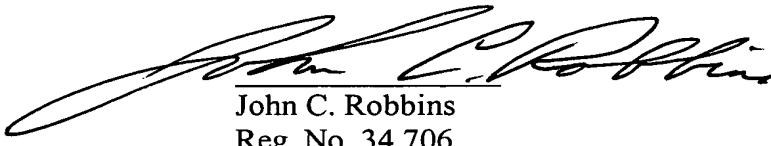
With respect to the rejections of claims 10-12, and 16-20, the Glastra et al. document in view of Jaeger et al. and the Tower reference fail to disclose these claims especially in view of the arguments above with respect to independent claim 1. Further, if one of ordinary skill in the art were to combine these references as suggested in the Office Action, the resulting hypothetical device would not result in a stent-catheter arrangement that would meet the claims. In particular, the hypothetical device would have stiffening elements formed on the stent and not on the catheter as claimed.

Therefore, Applicant respectfully requests that this rejection be withdrawn in view of the above comments and amendments.

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In view of the foregoing amendment and comments, Applicant respectfully asserts that claims 1-3 and 8-20 are now in condition for allowance. Reexamination and reconsideration of the pending claims are respectfully requested.

Respectfully submitted,



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